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|-----------------|-------------|----------------------|---------------------|------------------|
| 09/683,710 | 02/05/2002 | Carsten Rosenow | 3394.1 | 6460 |

22886 7590 07/23/2003

AFFYMETRIX, INC
ATTN: CHIEF IP COUNSEL, LEGAL DEPT.
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SANTA CLARA, CA 95051

EXAMINER

STRZELECKA, TERESA E

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1637

DATE MAILED: 07/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/683,710

Applicant(s)

ROSENOW, CARSTEN

Examiner

Teresa E Strzelecka

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-20 is/are rejected.
- 7) ☒ Claim(s) 17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 February 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group IV (claims 17-20) in Paper No. 3 is acknowledged.
2. Claims 1-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 3.

Priority

3. Applicant claims priority to a provisional application No. 60/266,718 with a filing date of February 5, 2001. The first paragraph of the specification contains an error in the filing date of the provisional application: February 2, 2001.

Drawings

4. The drawings are objected to under 37 CFR 1.83(a) because they fail to show the following details: in Fig. 1 and 2, annotations at the bottom of the figures are superimposed on black bars, making them illegible. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

5. The disclosure is objected to because of the following informalities:
 - A) The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or

other form of browser-executable code. See MPEP § 608.01. The hyperlink is present on page 25, [0074].

B) The specification contains references to Table 3 (page 24, [0073]) and Table 5 (page 26, [0075]). These tables were not provided with the specification.

Appropriate correction is required. No new matter should be introduced.

Incorporation by reference

6. Applicant indicated on page 3, [0013], that all references, including patents and non-patent literature are incorporated by reference. On page 4, [0017], Applicant cites laboratory manuals. and makes a statement that all of the are incorporated by reference. On page 5, the last line of [0020], Applicants states that a publication of Kaneisha is incorporated by reference. On page 12, the last line of [0042], Applicants states that a publication of Fodor et al. is incorporated by reference. It is not clear whether all of these non-patent publications constitute essential or non-essential matter.

7. The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

8. If the publications cited constitute a non-essential material, Applicant should include a statement to this effect (see MPEP 608.01(p), part A of which is cited below).

MPEP 608.01(p).

Art Unit: 1637

A. Review of Applications Which Are To Issue as Patents.

An application as filed must be complete in itself in order to comply with 35 U.S.C. 112. Material nevertheless may be incorporated by reference, *Ex parte Schwarze*, 151 USPQ 426 (Bd. App. 1966). An application for a patent when filed may incorporate "essential material" by reference to (1) a U.S. patent, (2) a U.S. patent application publication, or (3) a pending U.S. application, subject to the conditions set forth below. "Essential material" is defined as that which is necessary to (1) describe the claimed invention, (2) provide an enabling disclosure of the claimed invention, or (3) describe the best mode (35 U.S.C. 112). In any application which is to issue as a U.S. patent, essential material may not be incorporated by reference to (1) patents or applications published by foreign countries or a regional patent office, (2) non-patent publications, (3) a U.S. patent or application which itself incorporates "essential material" by reference, or (4) a foreign application.

Nonessential subject matter may be incorporated by reference to (1) patents or applications published by the United States or foreign countries or regional patent offices, (2) prior filed, commonly owned U.S. applications, or (3) non-patent publications however, hyperlinks and/or other forms of browser executable code cannot be incorporated by reference. See MPEP § 608.01. Nonessential subject matter is subject matter referred to for purposes of indicating the background of the invention or illustrating the state of the art.

Claim Objections

9. Claim 17 is objected to because of the following informalities: typographical error in line 2, "derived". Appropriate correction is required.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. Claim 20 recites the limitation "the plurality of nucleic acid probes" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 19, from which claim 20 depends, contains a limitation "the probes".

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

14. Claims 17-20 rejected under 35 U.S.C. 102(e) as being anticipated by Shoemaker et al. (US 2002/0045169 A1).

Regarding claim 17, Shoemaker et al. teach detection of intergenic regions using an array of probes tiled across genomic sequences (Fig. 1; page 5, [0059]). The coding (= exons) and intergenic regions (= introns, untranslated regions) are detected by hybridizing a sample containing transcripts (= mRNA) or nucleic acids derived from transcripts (= cDNA) (page 8, 9 [0088]; page 9, [0094]-[0096]). In a preferred embodiment, 60 bp probes are used (page 6, [0068]), with overlap in a range of 5 to 20 bp or larger (page 6, [0069]). Shoemaker teach classifying non-coding regions as 5' or 3' UTRs based on the fact that they are co-transcribed with exons and contained within the same transcript (page 13, [0130]). Shoemaker et al. teach detection of a 3' UTR region of an unknown gene in a testis-specific mRNA (page 19, [0177]; Fig. 14). Shoemaker et al. do not specifically teach that the intergenic region is transcribed in the same orientation as the gene, but since the probed transcript was a single transcript, the property that the 3' UTR was transcribed in the same orientation is inherent. Shoemaker et al. do not specifically teach that the transcript has to be greater than 70 bp. However, as shown in Fig. 14, the 60 bp probes are tiled at 10 bp intervals, therefore the minimum length of a transcript would have to be 70 bp, if it were to be detected by at least two probes.

Regarding claim 18, Shoemaker et al. teach probes immobilized on a solid support (= substrate) (page 5, [0058]; page 8, [0083]).

Regarding claims 19 and 20. Shoemaker et al. teach probe density of at least 550 different probes per cm² or at least 1000 different probes (page 5, [0062]).

15. No claims are allowed.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (703) 306-5877. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

TS
July 21, 2003

TS


BJ FORMAN, PH.D.
PRIMARY EXAMINER